Mpox Overview for HIV/AIDS Providers

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Outline

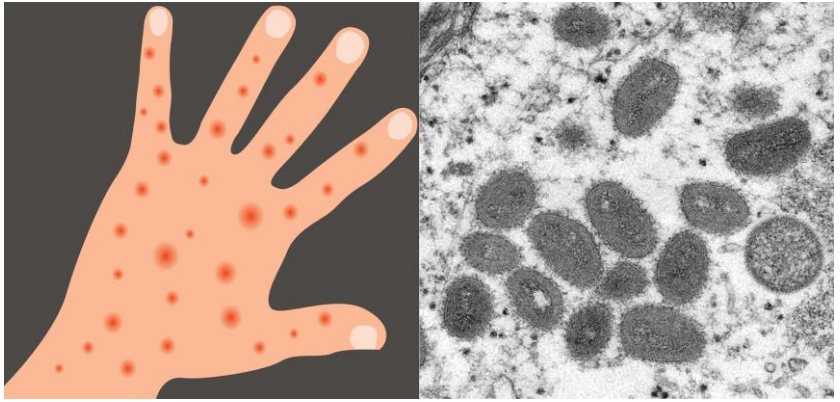
1. General Overview
2. Clinical Assessment & Evaluation
3. Infection Prevention & Control for Healthcare Settings
4. Testing
5. Vaccination
6. Treatment & Patient Management

High yield resources for clinicians:

- CDC Information For Healthcare Professionals
- VDH Mpox Healthcare Provider Webpage
- Clinical Considerations for Treatment and Prophylaxis of Mpox Virus Infection in People who are Immunocompromised

General Overview

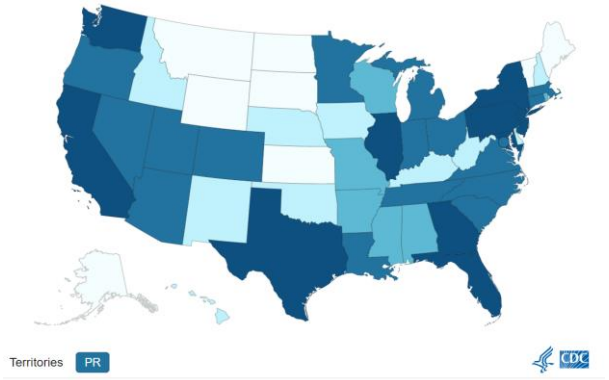
About Mpox



- Caused by *monkeypox virus*
- Same family of viruses as smallpox
- Two clades
  - Clade I: more severe illness
  - Clade II: current global outbreak
- Symptoms similar to smallpox, but milder illness
- Rarely fatal
- Not related to chickenpox

cdc.gov/poxvirus/monkeypox/response/2022/world-map.html

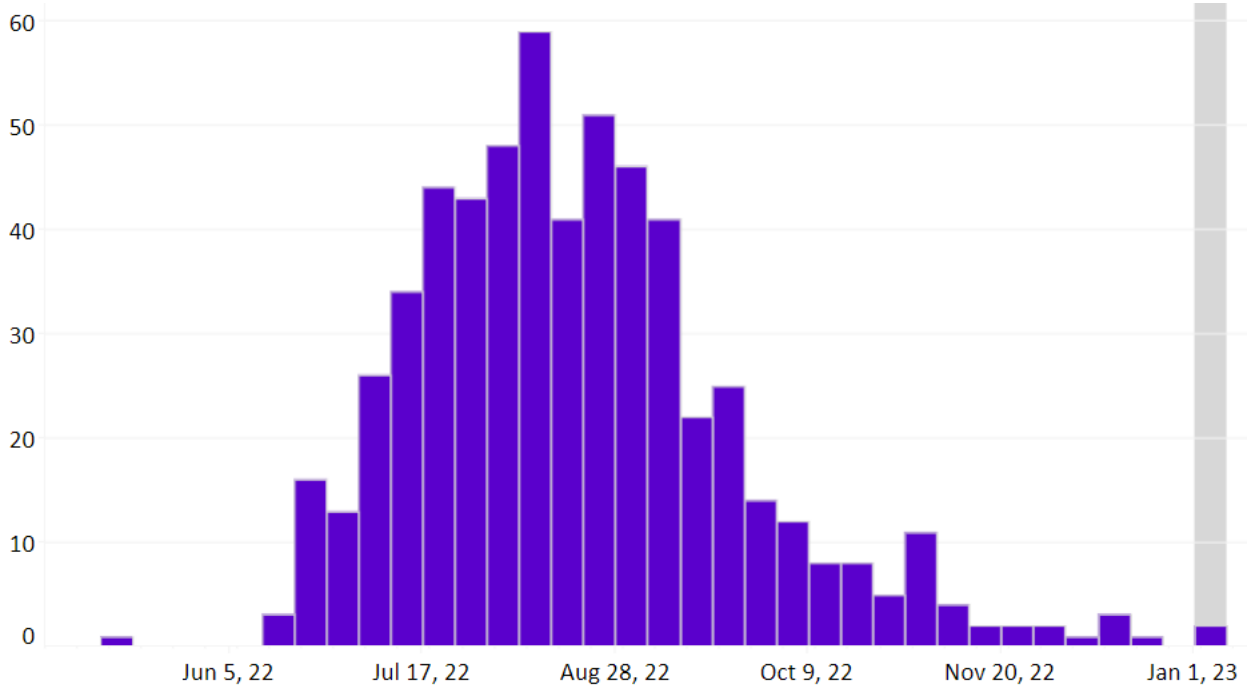
2022 Mpox Outbreak



- Multinational outbreak of mpox
- MMWR summary of U.S. cases (May-July 2022)
  - 99% have occurred in men
  - 94% of whom reported recent intimate or sexual contact with other men
  - 41% had HIV infection
- Reported cases as of 1/11/2023
  - 84,648 cases reported from 110 countries in the world
  - 29,980 cases in the U.S.
- As of 1/11/2023, 21 fatal cases in the U.S.

cdc.gov/poxvirus/monkeypox/response/2022/us-map.html

Data in Virginia



As of 1/13/2023:

- 568 confirmed cases
- 30 hospitalizations
- 1 death
- 95% in males
- Younger age groups (20-29, 30-39 years)
- Majority have reported race/ethnicity as Black, followed by white and Latino

vdh.virginia.gov/monkeypox/data-in-virginia/

Mpox Transmission

- Close contact with rash lesions or body fluids
  - Can occur during intimate contact
- Can also spread via contaminated materials (*e.g.*, bedding, towels) or large respiratory droplets
- Most cases in people who identify as men who have sex with men
  - Anyone can get and spread mpox through close contact
- Incubation Period: 3-17 days - unknown if this is different in people with HIV
- People are infectious from symptom onset until skin lesions have scabbed over, scabs have fallen off, and new skin has formed
- Spread from infected person to dogs reported but very rare
- Currently unknown whether HIV infection alters a person's risk of acquiring mpox after exposure

Scientists Researching Transmission Routes

- How often the virus can be spread when someone has no symptoms
- How often does mpox spread through respiratory secretions, or when a person with mpox symptoms might be more likely to spread the virus through respiratory secretions
- If it can spread via semen, vaginal fluids, urine, or feces

Clinical Assessment & Evaluation

Clinical Features

- Prodrome
  - Fever, chills, headache, myalgia, back pain, fatigue, lymphadenopathy
  - Present before or after rash, or absent
- Rash 1–3 days after prodrome
  - Oral mucosal lesions
  - Cutaneous lesions progress through stages - macules, papules, vesicles, pustules, scabs
- Generally self-limited illness, lasts 2–4 weeks
  - Lesions can be very painful, itchy
- See CDC's mpox Clinical Recognition webpage
- Symptoms/signs are similar in people with or without HIV
- Data indicate that people with advanced and uncontrolled HIV disease can be at higher risk of severe or prolonged mpox infection - same is true for people who are immunocompromised in general

Key Rash Characteristics in Outbreak

- Well circumscribed, firm, deep-seated lesions, often develop umbilication
- Lesions often in genital and anorectal areas or in mouth
- Rash not always disseminated across many sites
- May only have a few lesions or even a single lesion
- Rash not always on palms and soles
- Rash can be confused with other illnesses

cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html

Distinguishing Mpox

- Mpox rash can be confused with STIs, especially if rash in genital and/or perianal area
- STI diagnosis does not exclude mpox infection
  - Concurrent infections with STIs have been reported
- Comprehensive evaluation
  - History of illness - prodrome, progression of rash, lesions may be painful or itchy
  - Social history clues
  - Thorough physical exam looking for centrifugal rash distribution (rash concentrated on face, arms, legs), lesions in same stage of development in an area, or umbilicated lesions
  - Patients with a new characteristic rash or who meet one or more of the epidemiologic criteria and in whom there is a high suspicion should be tested for mpox

Clinical Presentation in Immunocompromised Individuals

Immunocompromised people, including people with advanced HIV or untreated HIV, may present with:

- Atypical rash, including a disseminated rash
- Severe rash or severe mucosal lesions
- Involvement of other organs (e.g., eyes, brain, lungs)
- In one study, people with poorly controlled HIV were more likely to have genital lesions and a confluent or partially confluent rash and prolonged illness.

Clinical Considerations for Treatment and Prophylaxis of Mpox in People who are Immunocompromised

Patient Evaluation & Diagnosis

- CDC Epidemiologic Criteria
  - **Close contact with someone with a rash or who received a diagnosis of confirmed or probable mpox**
  - **Sexual or intimate contact with individuals in a social network experiencing mpox activity**
  - Travel to a country with recent mpox cases or prior outbreak
- Isolate patient - standard and transmission-based precautions
- Contact local health district immediately to report suspected case, either by telephone or using the Confidential Morbidity Report Portal
- LHD Locator: vdh.virginia.gov/health-department-locator/
- Testing for mpox

Resources: Clinical Assessment & Evaluation

- Clinical Considerations for Treatment and Prophylaxis of Mpox Infection in People Who are Immunocompromised
- VDH Mpox for Healthcare Providers
- CDC Clinical Recognition
- CDC Clinical Considerations for Mpox in Children and Adolescents
- CDC Signs and Symptoms
- What You Need to Know about Mpox if You are a Teen or Young Adult (print resource)
- CDC What Clinicians Need to Know About Monkeypox in the United States and Other Countries (COCA webinar)

Infection Prevention & Control for Healthcare Settings

Infection Prevention & Control Recommendations: Evaluating a Person Suspected to Have Mpox - 1

- Isolate patient in a single room. Special air handling not required
  - Patient should be masked and lesions covered in shared spaces
- HCP should use standard and transmission-based precautions
  - PPE: gown, gloves, N95 respirator, eye protection (goggles or face shield that covers the front and sides of the face)
  - Any procedures likely to spread oral secretions (intubation, extubation, etc.) should be performed in an airborne infection isolation room
- Avoid activities that may spread material from lesions
  - Soiled laundry should be gently and promptly contained; avoid shaking or handling in a manner that may disperse infectious material
  - Avoid use of portable fans, dry dusting, sweeping, and vacuuming

cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html

Infection Prevention & Control Recommendations: Evaluating a Person Suspected to Have Mpox - 2

- When testing, collect specimens following CDC IPC guidance
- Manage waste according to U.S. Department of Transportation (DOT) Hazardous Materials Regulations and state and local regulations
  - If patient does **not** have known epi risk for *monkeypox virus* Clade I exposure (e.g., history of travel to the Democratic Republic of the Congo (DRC), the Republic of Congo, the Central African Republic, Cameroon or Gabon in prior 21 days), patient waste may be managed as Regulated Medical Waste.
  - If patient has risk for Clade I exposure, waste should be managed as Category A pending clade confirmation.

cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html

Patients with Mpox: Isolation & Prevention Practices in a Non-healthcare Setting - 1

- CDC recommends that people with mpox isolate at home or another location for the duration of the illness
- Current data suggest that people are contagious from the time symptoms start until all symptoms are resolved and all skin lesions are fully healed
- Typical duration of isolation is 2-4 weeks

cdc.gov/poxvirus/monkeypox/clinicians/isolation-procedures.html

Patients with Mpox: Isolation & Prevention Practices in a Non-healthcare Setting - 2

If patients are not able to isolate fully for the duration of the illness, CDC recommends the following:

- While the patient is symptomatic with fever and any respiratory symptoms, they are advised to remain isolated - patients are advised to avoid close or physical contact with other people or animals
- Cover the skin lesions, wear a well-fitting mask, and avoid public transportation
- If a rash persists in the absence of fever or respiratory symptoms, it's recommended that all parts of the rash be covered with clothing, gloves, and/or bandages. Patients should also wear a well-fitting mask to prevent the spread of oral and/or respiratory secretions

cdc.gov/poxvirus/mpox/clinicians/isolation-procedures.html

Patients with Mpox: Isolation & Prevention Practices in a Non-healthcare Setting - 3

- Until all signs and symptoms of mpox illness have fully resolved, patients should be advised about the following:
  - Do not share items that have been worn or handled with other people or animals. Launder or disinfect items that have been worn or handled and surfaces that have been touched by a lesion.
  - Avoid close physical contact, including sexual and/or close intimate contact, with other people.
  - Avoid sharing utensils or cups. Items should be cleaned and disinfected before use by others.
  - Avoid crowds and congregate settings.
  - Wash hands often with soap and water or use an alcohol-based hand sanitizer, especially after direct contact with the rash.

cdc.gov/poxvirus/monkeypox/clinicians/isolation-procedures.html

Patients with Mpox: Isolation & Prevention Practices in a Non-healthcare Setting - 4

- The recommendations on the previous slide can also apply to the workplace. Employers can learn more on the Workplaces and Businesses Toolkit webpage
- Employers can take actions to prevent the spread of mpox in the workplace
  - Ensure that workers with mpox follow the isolation practices
  - Offer telework or flexible, non-punitive sick leave to workers with mpox

cdc.gov/poxvirus/monkeypox/clinicians/isolation-procedures.html

Patients with Mpox: Isolation & Prevention Practices in a Non-healthcare Setting - 5

- Routinely clean and disinfect commonly touched surfaces and items, such as counters or light switches, using an EPA-registered disinfectant (such as List Q) in accordance with the manufacturer's instructions.
- Avoid use of contact lenses to prevent inadvertent infection of the eye.
- Avoid shaving rash-covered areas of the body as this can lead to spread of the virus.
- Bathroom usage:
  - If possible, use a separate bathroom if others live in the same household.
  - If no separate bathrooms in the home, patient should clean and disinfect surfaces such as counters, toilet seats, faucets, using an EPA-registered disinfectant (such as List Q) after using a shared space. This may include during activities like showering, using the toilet, or changing bandages that cover the rash. Consider disposable glove use while cleaning if rash is present on the hands.
- Limit contamination within household:
  - Try to avoid contaminating upholstered furniture and other porous materials that cannot be laundered by placing coversheets, waterproof mattress covers, blankets, or tarps over these surfaces.
  - Additional precautions such as steam cleaning can be considered if there is concern about contamination.

www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-home.html

Mpox Prevention & Infection Control in People with HIV

- People with HIV should follow the same mpox prevention measures as anyone else
  - Avoid direct contact with rashes, sores, or scabs on a person with mpox, including during intimate contact such as sex.
  - Avoid contact with objects, fabrics (for example, clothing, bedding, or towels), and surfaces that have been used by someone with mpox.
  - Avoid contact with respiratory secretions, through kissing and other face-to-face contact from a person with mpox.
- Infection control practices for the care of people with mpox are the same regardless of HIV status

Source: www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html

Resources: Infection Prevention & Control

- Isolation and Prevention Practices for People with Mpox
- Infection Prevention and Control of Mpox in Healthcare Settings
- Isolation and Infection Control at Home
- Monitoring and Risk Assessment for Persons Exposed in the Community

Testing

Testing

- Multiple commercial labs offer testing
  - Aegis, LabCorp, Mayo Medical Labs, and Sonic Healthcare use CDC's PCR test to detect non-variola orthopoxviruses; Quest uses its own dual target PCR test to detect non-variola orthopoxvirus and mpox viral DNA
  - Not free, out-of-pocket costs vary
  - Refer to lab for ordering and specimen collection information
  - Positive specimens might be sent to CDC for additional characterization
- Public health testing at Division of Consolidated Lab Services (DCLS)
  - Free if patients meet clinical and epidemiologic criteria
  - **Preapproval by LHD is required**
- **Patients suspected of having mpox (or who have the illness) should be tested for HIV and other STIs (gonorrhea, syphilis, herpes, chlamydia)**
- Immediately report any suspected mpox case to Local Health District
  - Use the Confidential Morbidity Report Portal (Epi-1) or telephone, even if testing is being conducted at a commercial laboratory.

Specimen Collection

- Wear appropriate PPE
- Collect material from surface of lesion or crust from healing lesion
- Collect 2 swabs from each lesion (2-3 lesions should be sufficient)
  - Prefer different locations or lesions that appear different
- Use sterile synthetic swabs with plastic, wood, or thin aluminum shaft
  - Do not use cotton swabs
- Swab surface of lesion **vigorously** to collect adequate DNA
  - **Do not need to de-roof or lance lesion before swabbing**
- Put each swab into separate container

cdc.gov/poxvirus/monkeypox/clinicians/prep-collection-specimens.html

Guidance if Patient Tests Positive

- Positive test from lab is actionable for clinical and epidemiologic purposes, do not need to wait for CDC confirmation
- Report to Local Health District, if haven't done so already
  - Use the Confidential Morbidity Report Portal (Epi-1) or telephone, even if testing is being conducted at a commercial laboratory.
- Evaluate patient for treatment
- Counsel patient to:
  - Notify close contacts
  - Stay home except for emergencies or medical care
  - Stay away from others in home, including pets
  - Avoid contact with others (including sexual contact)
  - Wear mask if have to be around others at home
  - Do not share items that could be contaminated (linens, clothing)
  - Do not use contact lenses
  - Wash hands often with soap and water or alcohol based hand sanitizer

Mpox Testing: Commercial Labs

	Quest	Labcorp	Aegis	Mayo	Sonic
Reference Website	monkeypox Virus DNA, Qualitative, Real-Time PCR | Quest Diagnostics	mpox (Orthopoxvirus), DNA, PCR Test | Labcorp	mpox Testing | Aegis Sciences Corporation (aegislabs.com)	MPXDX - Overview: Orthopoxvirus Molecular Detection PCR, Swab (mayocliniclabs.com)	mpox | Sonic Reference Laboratory
Test Code	12084	140230	06575		Contact the laboratory partner: Our Divisions | Sonic Healthcare USA
Expected Turnaround	2-3 days	3-4 days	24 hours	2 to 5 days	2-3 days
Additional Information	Quest Collection Guide	Labcorp Collection Instructions			

Last updated 1/10/2023. Please refer to the individual lab website for the most updated information.

Resources: Testing

- Guidelines for Collecting and Handling Specimens for Mpox Testing
- CDC Testing Patients for Monkeypox (print resource)
- CDC Tips for Adequate Collection of a Lesion Specimen from a Suspect Monkeypox Virus Case
- NETEC How to Collect a Monkeypox Specimen for Diagnostic Testing (VIDEO)
- NETEC Mpox Specimen Collection - VIDEO
- NETEC Mpox Specimen Collection - Breaking the Swab Shaft - VIDEO

Vaccination

Public Health Emergency Declaration

- HHS announced in August 2022
- Expected to end January 31, 2023 due to low number of mpox cases reported currently
- May affect availability and distribution of medical countermeasures like vaccines and treatment
- VDH Vaccine and Treatment websites will be updated with most recent information

Available Vaccines for Mpox

- Two vaccines available for preventing smallpox and mpox infection
- JYNNEOS™
  - Replication deficient, live attenuated *vaccinia* virus vaccine
  - FDA approved in 2019 for prevention of smallpox and mpox in people aged ≥18 years
  - Authorized for individuals less than 18 years of age under an FDA Emergency Use Authorization for prevention of mpox and also for intradermal (ID) use if ≥18 years

- ACAM2000®
  - Replication competent live *vaccinia* virus vaccine
  - Licensed in 2007 for people at high-risk for smallpox infection
  - Not approved or authorized by FDA for use for mpox prevention, use must be approved by CDC under an Expanded-Access Investigational New Drug (EA-IND) protocol
  - Should not be given to people with HIV, regardless of immune status

Currently, JYNNEOS is the primary vaccine being used in Virginia

JYNNEOS

- Two-dose series, separated by four weeks
- Considered vaccinated two weeks after receipt of second dose
- Booster doses may be recommended for ongoing occupational exposure
- No visible “take” so no risk for spread to other body parts or people
- Vaccination is NOT required for healthcare workers who will administer the vaccine
- Contraindication: history of severe allergic reaction to previous dose
- Precautions: severe allergic reaction to gentamicin or ciprofloxacin, OR history of severe allergic reaction to chicken or egg protein AND currently avoiding exposure to all chicken or egg products
- JYNNEOS ***is*** recommended for immunocompromised persons, including people with HIV and/or AIDS

JYNNEOS Emergency Use Authorization (EUA)

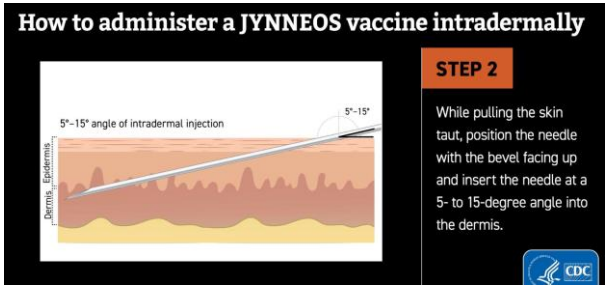
EUA (8/9/22) for immunization of those at high risk for mpox infection:

JYNNEOS vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
Alternative regimen				
People age ≥18 years	ID	0.1 mL	2	28 days
Standard regimen				
People age <18 years	Subcut	0.5 mL	2	28 days
People of any age who have a history of developing keloid scars	Subcut	0.5 mL	2	28 days

- **18 years of age and older:** should receive an **intradermal** injection. There are 2 exceptions to intradermal administration:
  - Those who have a contraindication to ID injection (e.g., those with a history of keloid formation or those unable to tolerate ID injections)
  - Those under 18 years of age
- **Under 18 years of age:** should receive **subcutaneous** injection only

Vaccine Administration Intradermal JYNNEOS

- ID administration: injecting vaccine superficially between epidermis & hypodermis layers of the skin, typically the volar aspect (inner side) of the forearm (other sites: deltoid, scapula)
- This should produce a noticeable pale elevation of the skin (wheal)
- ID route preferred, but patients can get SQ route if concerns about stigma or other reasons



CDC PDF Training
YouTube ID Video

Vaccine Effectiveness

- Initial data show reduced risk of mpox after 1 or 2 doses of JYNNEOS along with reduced risk of and hospitalization after 1 dose.
- Duration of protection from JYNNEOS vaccination is not known
- CDC continues to work its partners to collect data on vaccine safety and vaccine effectiveness
- Peak immunity is expected 14 days after the second dose of JYNNEOS and 4 weeks after vaccination with ACAM2000.
- People who are vaccinated are encouraged to continue to take steps to protect themselves
    - Avoid close, skin-to-skin contact with people who have a rash that looks like mpox
    - Avoid contact with objects and materials that a person with mpox has used
    - Wash hands often

cdc.gov/mmwr/volumes/71/wr/mm7149a5.htm
cdc.gov/mmwr/volumes/71/wr/mm715152a2.htm

Vaccination strategies & eligibility to prevent mpox – 1

Following a known exposure to a confirmed mpox case = use JYNNEOS for postexposure prophylaxis

- During days 0-4 after exposure, vaccination of contacts with an intermediate and high degree of exposure may prevent illness onset
- During days 4-14 after exposure, vaccination of contacts with a high degree of exposure may reduce symptoms of disease, but may not prevent it
- During days 4-14 after exposure, vaccination of contacts with an intermediate degree of exposure should be done based on informed decision making to determine whether it is felt that the benefit of the vaccine outweighs the risk

Vaccination strategies & eligibility to prevent mpox – 2

- Those with certain risk factors and recent experiences that might make them more likely to have been recently exposed to mpox:
  - Person (of any sexual orientation or gender) who has had anonymous or multiple (more than 1) sexual partners in the last 2 weeks
  - Person (of any sexual orientation or gender) diagnosed with any sexually transmitted infection in the past three months
  - Person (of any sexual orientation or gender) who is living with HIV/AIDS
  - Staff (of any sexual orientation or gender) at establishments or events where sexual activity occurs
  - Sex workers (of any sexual orientation or gender)

- **Persons living with HIV or other immune-compromising conditions may be at higher risk for severe outcomes and should be a high priority for vaccination.**

Vaccination strategies & eligibility to prevent mpox – 3

- **At this time, CDC recommendation is that most clinicians and laboratorians are not advised to be vaccinated for mpox.**

- The following groups are eligible for vaccination based on CDC recommendations:

    - Clinical lab personnel who perform testing to diagnose orthopoxviruses, including PCR assays to diagnose orthopoxviruses
    - Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopoxviruses that infect humans
    - Certain designated healthcare and public health response team members for preparedness purposes (i.e., those who will administer ACAM2000)

Providers Wanting to Administer JYNNEOS

- States get allocations based on **underlying population who may benefit** (i.e., HIV+, gay, bisexual, other men who have sex with men (MSM), eligible for HIV PrEP)
- At this time, majority of vaccines will be available at local health districts and select community partners who are more likely to care for high-risk individuals.
- To enroll as a mpox vaccine provider, please complete the following:
  - Review HHS Provider Agreement to understand requirements of mpox vaccine providers and prepare to attest to requirements.
  - Watch the following 7-minute video: VERIP (Virginia Electronic Registration for Immunization Programs) Training Video
  - Email the VaxMaX Help Desk at vaxmax_help@vdh.virginia.gov to declare intent to order and administer the mpox vaccines in accordance with the HHS Provider Agreement requirements. VaXMaX will provide next steps for attestation.
  - Review the following VDH resources that may be adapted to fit your practice site.

    Consent Form Template
    Intradermal Injection Training Resources
    Statewide monkeypox standing order
    Vaccination Checklist
    Vaccine Guide for Private Providers (VDH)

- Report vaccine doses administered in VIIS; report adverse events to VAERS

HHS Mpox Vaccination Provider Agreement
VDH Vaccine Guidance for Healthcare Providers

Resources: Vaccine

Helpful Clinician Resources:

- Vaccine Administration Errors and Deviations
- Vaccination Interim Guidance
- Dosing Intervals
- Vaccine Administration
- Interchangeability of Dosing Regimens
- JYNNEOS Coadministration with Other Vaccines
- Patient Counseling
- Vaccine Administration in Special Populations
- Reporting of Adverse Events
- General best practice guidelines for immunization
- Clinician FAQs

Vaccine Resources:

- JYNNEOS Package Insert
- JYNNEOS Vaccine Information Statement (VIS)
- JYNNEOS Storage and Handling Summary
- JYNNEOS Standing Orders (Standard Regimen)
- JYNNEOS Standing Orders (Alternative Regimen)
- JYNNEOS Preparation and Administration Summary (Standard Regimen)
- JYNNEOS Preparation and Administration Summary (Alternative Regimen)
- FDA EUA Fact Sheet for Providers
- FDA EUA Fact Sheet for Patients and Caregivers

Treatment & Patient Management

Mpox Treatment Considerations

- Many individuals infected have mild, self-limiting course
- No treatment specifically approved for mpox virus infections, but antiviral drugs used for smallpox may be beneficial
- Treatment may be considered in people with:
  - **Severe disease** (i.e., hemorrhagic disease, confluent lesions, sepsis, encephalitis, ocular or periorbital infections, or other conditions requiring hospitalization)
  - **Involvement of anatomic areas which might result in serious sequelae** (including scarring or strictures), including lesions directly involving the pharynx; penile foreskin, vulva, vagina, urethra, or rectum; anal lesions; and severe infections (including secondary bacterial skin infections)
  - **High risk of severe disease** (i.e., in patients with immunocompromising conditions including HIV/AIDS, patients <8 years of age, pregnant/breastfeeding, people with a condition affecting skin integrity, such as atopic dermatitis)

CDC Treatment Information for Healthcare Professionals

Mpox Treatment Considerations in People with HIV

- People with HIV may be at increased risk of severe disease and prolonged infectiousness.
  - Treatment and close monitoring are a priority for this population
  - Use clinical judgment and consider CD4 count and viral suppression in assessing the degree of immunosuppression and risk of severe outcomes from mpox.
- Antiretroviral therapy (ART) and opportunistic infection prophylaxis should be continued in all people with HIV who develop mpox - treatment interruption could lead to complications
- People taking antiretrovirals for HIV pre-exposure prophylaxis (PrEP) or postexposure prophylaxis (PEP) should not stop these medications
- For people with HIV diagnosed coincident with mpox or who are not taking ART, CDC recommends starting ART as soon as possible, and in consultation with an expert in HIV medicine if needed.
- Clinicians using antiviral medication for mpox need to be alert for potential drug-drug interactions with antiretrovirals used to treat or prevent HIV

Clinical Considerations for Treatment and Prophylaxis of Mpox Virus Infection in People who are Immunocompromised

Treatment Options

- **Tecovirimat (TPOXX) is the preferred antiviral treatment**
- Can be accessed through the federal government's Strategic National Stockpile under an Expanded Access-IND protocol

Treatment Option	Indication	Formulations Available
Tecovirimat (TPOXX or ST-246) *antiviral	Per EA-IND, for patients with laboratory confirmed non-variola orthopoxvirus infection or suspected infection based on known exposure(s) and/or clinical manifestations of disease	Oral (200 mg capsule)* Injection for intravenous administration *ability to mix with semi-solid food for pediatrics < 13 kg
Cidofovir (Vistide) *antiviral	FDA approved for treatment of cytomegalovirus retinitis in patients with AIDS	Intravenous infusion single-unit vial
Vaccinia Immune Globulin Intravenous (VIGIV)	FDA licensed for treatment of complications due to vaccinia vaccination	Intravenous infusion single-dose vial
Brincidofovir (Tembexa) *antiviral	FDA approved for the treatment of smallpox in adults and pediatrics, including neonates Drug is available through an FDA-authorized single patient emergency use IND (e-IND)	Oral (100 mg tablet or 10 mg/mL suspension)

TPOXX Treatment

- TPOXX is FDA-approved treatment of smallpox in adults and children
- Data on effectiveness in treating mpox infections in humans are not available
  - Animal studies showed effective in treating disease caused by orthopoxviruses
  - A case series of individuals infected with *monkeypox vir*us, which included one patient treated with tecovirimat, suggests that tecovirimat may shorten the duration of illness and viral shedding (Lancet 2022)
- Clinical trials in people showed drug was safe and had only minor side effects
  - Common adverse reactions with oral treatment: headache (12%), nausea (5%), abdominal pain (2%), and vomiting (2%)
- Drug-drug interactions have been reported with repaglinide (hypoglycemia) and midazolam (decreased effectiveness of midazolam).
- If there is an appropriate clinical indication, empiric treatment can be considered prior to laboratory confirmation, especially in the context of limited or delayed testing.

cdc.gov/poxvirus/monkeypox/clinicians/treatment.html

Considerations with TPOXX

- Clinicians and patients should understand:
  - Lack of tecovirimat effectiveness data in people with mpox
  - Lack of data indicating which patients might benefit the most
  - Concern for the development of resistance which could render the drug ineffective for any treated patients
- Recent FDA data suggest there may be a low barrier to virus developing resistance to tecovirimat
  - Indiscriminate use could promote resistance
- Recent CDC Health Update on November 17 reported two cases of lab-confirmed TPOXX resistance
- Alternate therapeutics have more concerning safety profiles than tecovirimat.

.cdc.gov/poxvirus/mokneypox/clinicians/Tecovirimat.html

Step-by-Step Instructions for TPOXX Treatment

The following steps are **required** to obtain and initiate TPOXX treatment:

1. Have the patient sign the **Informed Consent Form** (English, other languages)
2. Complete the VDH **TPOXX Provider Treatment Initiation Interest Form** **that includes details on shipping to patient, provider office, or provider office for provider dispensement (labels drug)**
3. Register on CDC TPOXX IND Online Registry and complete electronically:
   - **Patient Intake Form** - required for each individual prescription
   - **FDA Form 1572** - only 1 signed form *per facility*
4. Complete the **TPOXX Inventory & Patient Initiation Survey** for **all** patients who are started on TPOXX
5. Report any life-threatening or serious adverse events associated with TPOXX by sending a completed **MedWatch Form** to regaffairs@cdc.gov within 72 hours of awareness

Optional Steps in TPOXX Treatment

The following steps in TPOXX treatment are **optional:**

1. Ideally during initial assessment, give Patient Diary to all patients and Instructions for mixing TPOXX capsules with food to those who cannot swallow capsules
2. Submit the Clinical Outcome Form to document progress during and after treatment
3. Submit samples: plasma for Pharmacokinetic Samples for Testing and Lesion Samples for Resistance Testing
4. Provide photos of lesions at baseline (before TPOXX treatment) and after treatment

Guidance and Supportive Care for Patients

- Educate patients on the natural course of mpox illness, isolation and infection prevention practices.
- All patients should be encouraged to eat healthy, stay hydrated, and rest.
- While most patients with mpox have a mild, self-limited course, all patients should be assessed and given supportive care for management of their symptoms.
  - Symptoms should be addressed early in management.
  - Supportive care includes maintenance of fluid balance, pain management, treatment of bacterial superinfections, co-occurring sexually transmitted, or superimposed bacterial skin infections.
  - Supportive care may require hospitalization in patients with dehydration, severe pain, or complications.

Monkeypox (mpox): Information for Providers (NYC Department of Health)

Clinical Considerations for Pain Management

- Healthcare professionals should assess pain in all patients with mpox virus infection and recognize that substantial pain may exist from mucosal lesions not evident on physical exam.
  - Topical and systemic strategies should be used to manage pain.
- General pain control: OTC medications (e.g., acetaminophen, NSAIDs)
- Local pain control: Topical steroids and anesthetics such as lidocaine
  - Topical lidocaine or other topical anesthetics should be used with caution on broken skin or on open or draining wounds.
- Prescription pain meds such as gabapentin and opioids have been used for short-term management of severe pain. Consider the risks/benefits.
- Appropriate pain control may require hospitalization.

CDC Clinical Considerations for Pain Management of mpox

Management of Rash and Skin Lesions

To prevent spread of the rash and risk of secondary bacterial infection, instruct patients to:

- Cover rash with gauze/bandages and wear long sleeves/pants, if possible.
- Try not to touch the rash, and don't pop or scratch lesions.
- Do not shave the area with the rash until the scabs have fallen off and a new layer of skin has formed.
- Keep skin lesions clean and dry when not showering or bathing.
- Wash hands often with soap and water or use an alcohol-based hand sanitizer, especially after direct contact with the rash.
- If you have rash on your hands, wear gloves when handling common objects or touching shared surfaces. Use disposable gloves if possible; if using reusable gloves, wash with soap and water between use.
- Avoid use of contact lenses (to prevent infection of the eye)

Management of Rash and Skin Lesions

- Instruct patients to monitor for any increased redness, warmth, or purulence around lesions and seek care if these develop.
- Pruritis: Oral antihistamines; topical agents such as calamine lotion, petroleum jelly, or colloidal oatmeal
- Oropharyngeal lesions: Clean saltwater gargle four times a day, oral antiseptic (e.g., chlorhexidine mouthwash), local anesthetic (e.g., viscous lidocaine), and prescription analgesic mouthwash (sometimes called “magic mouthwash”)
- Genital/ anorectal lesions: Warm sitz baths, for 10 minutes several times a day. Adding Epsom salt, vinegar, or baking soda to the water may be helpful.
    - Sitz baths should be drained and disinfected after use to mitigate risk of autoinoculation or person to person transmission.

Resources: Treatment

- CDC Treatment Information for Healthcare Professionals
- CDC Clinical Considerations for Pain Management of Mpox
- CDC Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Mpox Outbreak
- CDC Information for Healthcare Providers: Tecovirimat (TPOXX) for Treatment of Mpox
- CDC Clinical Considerations for Treatment and Prophylaxis of Mpox Virus Infection in People who are Immunocompromised
- CDC What To Do If You Suspect mpox

CDC can assist physicians in the diagnosis and management of patients with suspected or confirmed mpox. If VIGIV or antivirals are needed, or additional information is required, physicians should contact the CDC Emergency Operations Center at 770-488-7100, Monday through Friday 8 AM to 4:30 PM Eastern Standard Time; at other times call (404) 639-2888.

Health Equity

- Mpox outbreak has disproportionately affected gay, bisexual and other men who have sex with men, also people of color, people with HIV, transgender and gender-diverse adults
  - Critical to ensure equity in treatment and vaccination
  - Recent publication and available data suggest racial and ethnic disparities in vaccination rates, especially among Black and Latino men
- CDC has launched Mpox Vaccine Equity Pilot Program
  - Community-based organizations in Virginia that are interested in participating should contact VDH
- CDC is supporting public health jurisdictions' vaccination initiatives at events focusing on general LGBTQ+ population, such as Pride festivals

www.cdc.gov/mmwr/volumes/71/wr/mm7132e3.htm?s_cid=mm7132e3_w
www.cdc.gov/poxvirus/monkeypox/response/2022/vaccines_data.html

Thank you for your attention!

Questions?